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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,646	01/13/2005	Berta Kotar Jordan	4061-25PUS	9299
27799	7590	05/22/2008		
COHEN, PONTANI, LIEBERMAN & PAVANE LLP				
551 FIFTH AVENUE				
SUITE 1210				
NEW YORK, NY 10176				
EXAMINER				
COLEMAN, BRENDA LIBBY				
ART UNIT		PAPER NUMBER		
1624				
MAIL DATE		DELIVERY MODE		
05/22/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/521,646

**Applicant(s)**

KOTAR JORDAN ET AL.

**Examiner**

Brenda L. Coleman

**Art Unit**

1624

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-9, 12-22, 24 and 26-28 is/are allowed.
- 6) ☒ Claim(s) 1-5, 10, 11, 23 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-28 are pending in the application.

This action is in response to applicants' amendment filed February 19, 2008.

Claims 1, 4, 11 and 15 have been amended.

### ***Response to Arguments***

Applicant's amendments filed February 19, 2008 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 2) of the last office action, which are hereby **withdrawn**.
2. With regards to the 35 U.S.C. § 102(b), anticipation rejection of claims 1-5, 10, 11 and 25, labeled paragraph 3) of the last office action. The applicants' arguments have been fully considered, however they were not found persuasive. As stated by the applicants "Bunnell describes the preparation of the solvate of olanzapine". The applicants' are also claiming a solvate of olanzapine as set forth in claim 4, which is further limiting of claim 1 from which it depends, thus the process and the 2-propanol solvate of claims 1-5, 10, 11 and 25.

Claims 1-5, 10, 11 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by BUNNELL et al., U.S. Patent No. 5,703,232, for reasons of record and stated above.

3. With regards to the 35 U.S.C. § 102(b), anticipation rejection of claim 23, labeled paragraph 4) of the last office action, the applicants' arguments have been fully considered, however they were not found persuasive. As stated by the applicants' "Claim 23 is directed to a pharmaceutical composition which comprises crystalline form A of olanzapine characterized by a particular x-ray diffraction pattern". It is the solid crystalline form of olanzapine that possesses the crystalline polymorph Form A characteristics. Thus the pharmaceutical composition must contain a solid form of the crystalline polymorph Form A olanzapine in the pharmaceutical composition in order that the characteristics of the polymorph be retained. However, the applicants are not specifically claiming solid pharmaceutical compositions, but a composition comprising crystalline Form A olanzapine. The specification on page 13 discusses for example a polymorphic form A of olanzapine can be formulated in a pharmaceutical composition in combination with one or more pharmaceutical acceptable excipients which can be either solid, semisolid or liquid. Claim 23 fails to specifically claim a solid pharmaceutical composition.

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by CHAKRABARTI et al., U.S. Patent No. 5,229,382, for reasons of record and stated above.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/  
Primary Examiner, Art Unit 1624